Electronic Version
Stylesheet Version v1.1.1

Description

Breath Freshening and Oral Cleansing Product

BACKGROUND OF INVENTION

[0001] There is considerable consumer demand for products that freshen breath and kill bacteria in the mouth. An oral product with breath freshening and bactericidal benefits is a convenient delivery for oral cleansing in the oral cavity and freshening breath.

[0002] Of course, breath freshening is a very important part of everyday life. In order to facilitate proper oral hygiene, oral cleansing and breath freshening practices should be conducted repeatedly throughout the day.

[0003] However, oral cleansing and breath freshening may be difficult or inconvenient at times, depending on the nature of the breath freshening desired and the situation in which the breath freshening must occur. Brushing, flossing, cleaning your tongue and gargling using a variety of devices and compositions are common oral care practices

well-suited for the privacy of one's home. But, such devices and compositions are less convenient to use away from the home where bathroom facilities might be scarce, unavailable or unsanitary.

[0004] It is known to incorporate active agents into oral products for the purpose of providing oral benefits including breath freshening and bactericidal properties. Such systems have the advantage of providing a rapid effect and convenient delivery.

SUMMARY OF INVENTION

[0005] The present invention relates to methods of freshening breath and oral cleansing. Furthermore, the present invention relates to the composition of, and methods of producing an oral product. Specifically, the present invention relates to oral products intended for bactericidal and breath freshening properties. More specifically, the present invention relates to a dentifrice, chewing gum, confection, lozenge, mouthwash, mouth spray or edible film containing an effective amount of combinations of essential oils which produce a synergistic effect of bactericidal properties for oral cleansing and breath freshening, by which the inventive composition effectively inactivates or kills oral bacteria and freshens breath through the con-

sumption of the dentifrice, chewing gum, confection, lozenge, mouth wash, mouths spray or edible film product.

[0006] In an embodiment of the present invention, the oral product is chewing gum or any variation, including but not limited to, bubble gums, pellets, gum balls or sticks. Chewing gums may be coated or not coated and be of a variety of flavors, shapes and sizes.

[0007] In an embodiment of this invention, the oral product is a confectionery composition including but not limited to hard candy, chewing candy, filled candy and pressed tablets.

[0008] In another embodiment of the present invention, the oral product is a thin edible film.

[0009] In another embodiment the oral product is a dentifrice.

Detailed Description

[0010] It is known to use chewing gum, confections and thin films as a vehicle for delivering components to the oral cavity which provide oral benefits such as breath freshening and bactericidal properties. Such systems have the advantage of providing a consumer with a convenient and inexpensive method for maintaining oral health and fresh

breath throughout the course of the day.

[0011] The present invention incorporates essential oils demonstrating synergism in bactericidal properties as the active component for breath freshening and oral bactericidal benefits. Examples of essential oils include cinnamic aldehyde, salicylaldehyde, citral, peppermint oil and spearmint oil, and these oils are known to have bactericidal and anti-fungal properties.

[0012] In vitro tests were conducted with three subgingival plaque bacteria associated with oral malodor. The MIC (Minimum Inhibitory Concentrations) study protocol follows. Chlorhexidine was used as a positive control and sterile water was used as a negative control. Combinations of two essential oils were prepared and selected from five different essential oils suspended in 10% methanol. The five essential oils were cinnamic aldehyde (W1), salicylaldehyde (W3), citral (W4), peppermint oil (W10) and spearmint oil (W11). Nine combinations of two essential oils were tested. These included: W1/W3, W1/W4, W3/W4, W1/W10, W1/W11, W3/W10, W3/W11, W4/W10 and W4/W11. 96 well microtiter plates were used for this study. Each well contained 5×10^5 colony forming units/ml of bacteria, serially diluted agents and bacterial growth

medium. All bacterial cultures were incubated at 37°C and stationary. Bacterial growth was estimated spectrophotometrically at 660 nm, after 48 hours. The MIC for each test bacteria was defined as the minimum concentration of test compound limiting turbidity to <absorbance at 660nm. The fractional inhibitory index (FIC) was computed and expressed as synergistic (<0.5), additive (0.5 to 2.0) or antagonistic (>2.0). The FIC computation is FIC = $[MIC_{A\text{-combined with B}}/MIC_{A\text{ alone}} + MIC_{B\text{ combined with A}}/MIC_{B\text{ alone}}]$, where A = first essential oil and B = second essential oil.

[0013] The test bacteria included gram positive supragingival plaque bacterium: Streptococcus mutans IB; and the subgingival plaque bacterium associated with oral malodor: Porphyromonas gingivalis and Fusobacterium nucleatum. S. mutans were grown routinely in brain heart infusion broth. The medium used for P. gingivalis consists of Trypticase Soy broth-Yeast extract medium supplemented with cysteine hydrochloride menadione, hemin and potassium nitrate. For F. nucleatum, shaedler broth was used. P. gingivalis and F. nucleatum were incubated at 37°C in an anaerobic grown chamber.

[0014] Results for S. mutans were as follows. A synergistic reac-

tion was observed when cinnamic aldehyde and salicylaldehyde (W1/W3). The combination of citral and peppermint oil appeared to be antagonistic and the remaining combinations demonstrated additive effects.

[0015] Results for P. gingivalis were as follows. All combinations, except for cinnamic aldehyde and citral, exhibited synergistic growth inhibitory activity against P. gingivalis with FIC values of below 0.5. Those that demonstrated FIC values below 0.25 included combinations of salicylaldehyde and citral, salicylaldehyde and peppermint oil and citral and peppermint oil. With citral and peppermint oil, when the combination is a 1:4 ratio, or 1:8 ratio, synergistic activity was observed. However, if the combination is greater than this ratio, such as 1:1 or 1:2, antagonism was noted. Therefore, the concentration of respective oils in a combination is very important to achieve synergism.

[0016] Results for F. nucleatum were as follows. Compared to the other two test bacteria, F. nucleatum appeared to be most sensitive to antimicrobial oils tested. Antagonism was observed when cinnamic aldehyde and spearmint oils were combined. All other combinations demonstrated synergistic grown inhibitory activities against this bacterium. The FIC values were mostly <0.25. With the combination of

salicylaldehyde and peppermint oil, when the ratio was 1:1, 1:2 or 2:1, synergistic activity was observed. However, if the peppermint oil is present greater than these ratios, antagonism was observed.

[0017] Throughout the specification, the combination of essential oils referred to and utilized in the present invention are combinations of pairs of two essential oils selected from the group consisting of: cinnamic aldehyde, salicylaldehyde, citral, peppermint oil and spearmint oil. The combinations of essential oils discussed are the following: cinnamic aldehyde & salicylaldehyde, cinnamic aldehyde & citral, salicylaldehyde & citral, cinnamic aldehyde & peppermint oilcinnamic aldehyde & spearmint oil, salicylaldehyde & peppermint oil, salicylaldehyde & spearmint oil, citral & peppermint oil, andcitral & spearmint oil.

[0018] The combinations of essential oils are prepared in ratios appropriate to providing an effective amount of synergistic antimicrobial activity. Citral and peppermint oil are effective when provided in ratios of 1:4 or 1:8. Ratio"s greater than this provide an antagonistic effect. For the salicylaldehyde and peppermint oil combination, the ratios of 1:1, 1:2 and 2:1 provided synergistic activity. If peppermint oil is in a greater proportion, then antagonism is

observed.

[0019] In an embodiment, the invention comprises a treatment method for reducing the number or activity of bacteria in the oral cavity comprising the steps of providing an oral composition comprising a combination of essential oils in an amount sufficient to kill or deactivate oral bacteria and causing a person in need of the treatment to consume the oral composition whereby the bacteria in the oral cavity of the person is reduced or inactivated by the treatment.

[0020] In an embodiment, the oral composition comprises additional breath freshening or oral health ingredients.

[0021] In an embodiment, the additional breath freshening or oral health ingredients comprise anti-microbial ingredients.

[0022] In an embodiment, the additional breath freshening or oral health ingredients comprise food acceptable salts of zinc or copper.

[0023] In an embodiment, the additional breath freshening or oral health ingredients comprise cooling agents.

[0024] In an embodiment, the additional breath freshening or oral health ingredients comprise pyrophosphate or polyphosphate.

[0025] In an embodiment, the oral composition is formulated to

deliver at least 0.005% concentration of the combination of essential oils to the oral cavity.

[0026] In an embodiment, the oral composition is formulated to deliver at least 0.01% concentration of the combination of essential oils to the oral cavity.

[0027] In an embodiment, the oral compositions is formulated to deliver at least 0.1% concentration of the combination of essential oils to the oral cavity.

[0028] There are several methods, which may be used to enhance the release of the combination of essential oils from the oral composition. In a chewing gum product, the gum base is hydrophilic which would facilitate the release of the combination of essential oils. In an oral composition, the combination of essential oils may be encapsulated, spray dried, formulated into the coating and combinations thereof.

[0029] In an embodiment of the present invention, an effective amount of the combination of essential oils is present for anti-microbial benefit is present in a chewing gum formulation. In an embodiment of the present invention, the amount of the combination of essential oils present is up to about 5% by weight of the chewing gum product. In an embodiment of the present invention, the amount of the

combination of essential oils is about 1% of the weight of the chewing gum product. In another embodiment, the combination of essential oils is present in the amount of about 0.25% by weight of the chewing gum product. In another embodiment, the combination of essential oils is present in the amount of about 0.01% by weight of the chewing gum product.

[0030] In general, a chewing gum composition typically comprises a waterbulk portion, a waterchewable grams base portion and typically waterflavoring agents. The waterportion dissipates with a portion of the flavoring agent over a period of time during chewing. The gum base portion is retained in the mouth throughout the chew.

[0031] The insoluble gum base generally comprises elastomers, resins, fats and oils, softeners and inorganic fillers. The gum base may or may not include wax. The insoluble gum base can constitute approximately 5% to about 95% by weight of the chewing gum, more commonly the gum base comprises 10% to about 50% of the gum, and in some preferred embodiments approximately 25% to about 35% by weight, of the chewing gum.

[0032] In a particular embodiment, the chewing gum base of the present invention contains about 20% to about 60% by

weight synthetic elastomer, up to about 30% by weight natural elastomer, about 5% to about 55% by weight elastomer plasticizer, about 4% to about 35% by weight filler, about 5% to about 35% by weight softener, and optional minor amounts (about 1% or less by weight) of miscellaneous ingredients such as colorants, antioxidants, etc.

[0033] Synthetic elastomers may include, but are not limited to, polyisobutylene with GPC weight average molecular weight of about 10,000 to about 95,000, isobutylene-isoprene copolymer (butyl elastomer), styrenecopolymers having styrene-butadiene ratios of about 1:3 to about 3:1, polyvinyl acetate having GPC weight average molecular weight of about 2,000 to about 90,000, polyisoprene, polyethylene, vinyl acetate vinyl laurate copolymer having vinyl laurate content of about 5% to about 50% by weight of the copolymer, and combinations thereof.

[0034] Preferred ranges for polyisobutylene are 50,000 to 80,000 GPC weight average molecular weight and for styreneare 1:1 to 1:3 bound styrene for polyvinyl acetate are 10,000 to 65,000 GBC weight average molecular weight with the higher molecular weight polyvinyl acetates typically used in bubble gum base, and for vinyl acetatelaurate, vinyl laurate content of 10

[0035] Natural elastomers may include natural rubber such as smoked or liquid latex and guayule as well as natural gums such as jelutong, lechi caspi, perillo, sorva, massaranduba balata, massaranduba chocolate, nispero, rosindinha, chicle, gutta hang kang, and combinations thereof. The preferred synthetic elastomer and natural elastomer concentrations vary depending on whether the chewing gum in which the base is used is adhesive or conventional, bubble gum or regular gum, as discussed below. Preferred natural elastomers include jelutong, chicle, sorva and massaranduba balata.

[0036] Elastomer plasticizers may include, but are not limited to, natural rosin esters such as glycerol esters or partially hydrogenated rosin, glycerol esters of polymerized rosin, glycerol esters of partially dimerized rosin, glycerol esters of rosin, pentaerythritol esters of partially hydrogenated rosin, methyl and partially hydrogenated methyl esters of rosin, pentaerythritol esters of rosin; synthetics such as terpene resins derived from alpha beta and/or any suitable combinations of the foregoing. The preferred elastomer plasticizers will also vary depending on the specific application, and on the type of elastomer which is used.

[0037] Fillers/texturizers may include magnesium and calcium

carbonate, ground limestone, silicate types such as magnesium and aluminum silicate, clay, alumina, talc, titanium oxide, mono-, di- and tri-phosphate, cellulose polymers, such as wood, and combinations thereof.

[0038] Softeners/emulsifiers may include tallow, hydrogenated tallow, hydrogenated and partially hydrogenated vegetable oils, cocoa butter, glycerol monostearate, glycerol triacetate, lecithin, mono and triglycerides, acetylated monoglycerides, fatty acids (e.g. stearic, palmitic, oleic and linoleic acids), and combinations thereof

[0039] Colorants and whiteners may include FD&C dyes and lakes, fruit and vegetable extracts, titanium dioxide, and combinations thereof.

[0040] The base may or may not include wax. An example of a wax gum base is disclosed in U.S. Patent No. 5,286,500, the disclosure of which is incorporated herein by reference.

[0041] In addition to a water insoluble gum base portion, a typical chewing gum composition includes a water soluble bulk portion and one or more flavoring agents. The water soluble portion can include bulk sweeteners, high intensity sweeteners, flavoring agents, softeners, emulsifiers, colors, acidulants, fillers, antioxidants, and other compo-

nents that provide desired attributes.

[0042] Softeners are added to the chewing gum in order to optimize the chewability and mouthfeel of the gum. The softeners, which are also known as plasticizers and plasticizing agents, generally constitute between approximately 0.5% to about 15% by weight of the chewing gum. The softeners may include glycerin, lecithin, and combinations thereof. Aqueous sweetener solutions such as those containing sorbitol, hydrogenated starch hydrolysates, corn syrup and combinations thereof, may also be used as softeners and binding agents in chewing gum.

[0043] Bulk sweeteners include both sugar and sugarless components. Bulk sweeteners typically constitute about 5% to about 95% by weight of the chewing gum, more typically, about 20% to about 80% by weight, and more commonly, about 30% to about 60% by weight of the gum. Sugar sweeteners generally include saccharide components commonly known in the chewing gum art, including but not limited to, sucrose, dextrose, maltose, dextrin, dried invert sugar, fructose, levulose, galactose, corn syrup solids, and the like, alone or in combination. Sugarless sweeteners include, but are not limited to, sugar alcohols such as sorbitol, mannitol, xylitol, hydrogenated starch

hydrolysates, maltitol, and the like, alone or in combination.

[0044] High intensity artificial sweeteners can also be used, alone or in combination, with the above. Preferred sweeteners include, but are not limited to, sucralose, aspartame, NAPM derivatives such as neotame, salts of acesulfame, altitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizinate, dihydrochalcones, thaumatin, monellin, and the like, alone or in combination. In order to provide longer lasting sweetness and flavor perception, it may be desirable to encapsulate or otherwise control the release of at least a portion of the artificial sweetener. Such techniques as wet granulation, wax granulation, spray drying, spray chilling, fluid bed coating, coacervation, and fiber extension may be used to achieve the desired release characteristics.

[0045] Combinations of sugar and/or sugarless sweeteners may be used in chewing gum. Additionally, the softener may also provide additional sweetness such as with aqueous sugar or alditol solutions.

[0046] If a low calorie gum is desired, a low caloric bulking agent can be used. Examples of low caloric bulking agents include: polydextrose; Raftilose, Raftilin; Fructooligosaccha-

rides (NutraFlora); Palatinose oligosaccharide; Guar Gum Hydrolysate (Sun Fiber); or indigestible dextrin (Fibersol). However, other low calorie bulking agents can be used.

[0047] A variety of flavoring agents can also be used, if desired. The flavor can be used in amounts of about 0.1 to about 15 weight percent of the gum, and preferably, about 0.2% to about 5% by weight. Flavoring agents may include essential oils, synthetic flavors or mixtures thereof including, but not limited to, oils derived from plants and fruits such as citrus oils, fruit essences, peppermint oil, spearmint oil, other mint oils, clove oil, oil of wintergreen, anise and the like. Artificial flavoring agents and components may also be used. Natural and artificial flavoring agents may be combined in any sensorially acceptable fashion. Flavoring may include a cooling agent to enhance the flavor and perceived breath freshening of the product. Cooling agents include menthol, ethyl p-menthane carboxamide, N,2,3 - trimethyl-2-isopryl-butanamide, menthyl glutarate FEMA 4006, menthyl succinate, menthol PG carbonate, menthol EG carbonate, menthyl lactate, menthone glyceryl ketal, menthol glyceryl ether, N-tertbutyl-p-menthane-3-carboxamide, p-menthane-3-carboxylic acid glycerol ester, methyl-

2-isopryl-bicyclo (2.2.1), heptane-2-carboxamide, menthol methyl ether and combinations thereof.

[0048] In addition, to the active ingredients of the present invention, additional active ingredients or medicaments may be added for various purposes. If the medicament or active is water soluble in the chewing gum, it preferably will include a base/emulsifier system which leads to the desired concentration of the medicament in the saliva (more hydrophilic balance). If the medicament or active is water insoluble, the chewing gum preferably includes a base/emulsifier system which leads to the desired concentration of the medicament in the saliva (more lipophilic balance).

[0049] In manufacturing the chewing gum including the active agent or ingredient, the active agent or medicament is added, preferably, early on in the mix. The smaller the amount of active ingredient used, the more necessary it becomes to preblend that particular ingredient to assume uniform distribution throughout the batch of gum. Whether a preblend is used or not, the active agent or medicament should be added within the first five minutes of mixing. For faster release, the active agent may be added late in the process.

[0050] Optionally, the chewing gum of the present invention may include additional breath freshening, anti-microbial or oral health ingredients. Food acceptable metallic salts selected from zinc and copper salts of gluconic acid, zinc and copper salts of lactic acid, zinc and copper salts of acetic acid, zinc and copper salts of citric acid and combinations thereof.

[0051] Anti-microbial essential oils and flavor components such as peppermint, methyl salicylate, thymol, eucalyptol, cinnamic aldehyde, polyphosphate, pyrophosphate and combinations thereof.

[0052] Dental health ingredients such as fluoride salts, phosphate salts, proteolytic enzymes, lipids, anti-microbials, calcium, electrolytes, protein additives, dental abrasives and combinations thereof.

[0053] In general, chewing gum is manufactured by sequentially adding the various chewing gum ingredients to a commercially available mixer known in the art. After the ingredients have been thoroughly mixed, the gum mass is discharged from the mixer and shaped into the desired form such as rolling sheets and cutting into sticks, extruding into chunks or casting into pellets, which are then coated or panned.

[0054] Generally, the ingredients are mixed by first melting the gum base and adding it to the running mixer. The base may also be melted in the mixer itself. Color or emulsifiers may also be added at this time. A softener such as glycerin may also be added at this time, along with syrup and a portion of the bulking agent. Further parts of the bulking agent are added to the mixer. Flavoring agents are typically added with the final portion of the bulking agent. Other optional ingredients are added to the batch in a typical fashion, well known to those of ordinary skill in the art.

[0055] The entire mixing procedure typically takes from five to fifteen minutes, but longer mixing times may sometimes be required. Those skilled in the art will recognize that many variations of the above described procedure may be followed.

[0056] Chewing gum base and chewing gum product have been manufactured conventionally using separate mixers, different mixing technologies and, often, at different factories. One reason for this is that the optimum conditions for manufacturing gum base, and for manufacturing chewing gum from gum base and other ingredients such as sweeteners and flavors, are so different that it has been

impractical to integrate both tasks. Chewing gum base manufacture, on the one hand, involves the dispersive (often high shear) mixing of difficult-to-blend ingredients such as elastomer, filler, elastomer plasticizer, base softeners/emulsifiers and sometimes wax, and typically requires long mixing times. Chewing gum product manufacture, on the other hand, involves combining the gum base with more delicate ingredients such as product softeners, bulk sweeteners, high intensity sweeteners and flavoring agents using distributive (generally lower shear) mixing, for shorter periods.

[0057] The following are examples of formulations of combination of essential oils in chewing gum. The examples are not intended to exclude other variations in formulations and the present invention is not limited to these formulations.

Table 1. Antimicrobial Gum Formulas (% by weight)

Ingredient	Example 1	Example 2	Example 3	Example 4	Example 5
Gum Base	26.00	26.00	26.00	27.5	27.5
Talc powder	3.00	3.00	3.00	3.00	3.00
Glycerine	0.50	0.50	0.50	0.50	0.50
Sorbitol	49.71	50.96	48.71	48.71	44.71
Glycerol	15.01	15.01	15.01	15.01	15.01

Mannitol	1.52	1.52	1.52	1.52	1.52
Maltitol	0.76	0.76	0.76	0.76	0.76
Water	1.18	1.18	1.18	1.18	1.18
Aspartarme	0.53	0.53	0.53	0.53	0.53
Color	0.01	0.01	0.01	0.01	0.01
Zein	0.04	0.04	0.04	0.04	0.04
NaOH	0.01	0.01	0.01	0.01	0.01
Acesul-phame Potassium	0.13	0.13	0.13	0.13	0.13
Combo of Es-sential Oils	1.50	0.25	2.50	1.00	5.00
Hydroxy-propyl-methyl-cellu-lose	0.10	0.10	0.10	0.10	0.10
Total %	100.00	100.00	100.00	100.00	100.00

Table 2. Antimicrobial Gum Formulas (% by weight)

Ingredient	Example 6	Example 7	Example 8	Example 9	Example 10
Gum Base	19.46	20.71	19.46	19.46	18.46
Sugar	62.13	62.13	61.13	62.63	61.63
Corn Syrup	15.57	15.57	15.57	15.57	13.57
Color	0.67	0.67	0.67	0.67	0.67
P.A.	0.67	0.67	0.67	0.67	0.67
Combo of Es-sential Oils	1.50	0.25	2.50	1.00	5.00
Total %	100.00	100.00	100.00	100.00	100.00

[0058] In an embodiment of the present invention, and effective amount for anti-microbial benefit of the combination of essential oils is present in an edible film formulation. In an embodiment of the present invention, the amount of the combination of essential oils present is up to 20% by weight of the edible film formulation. In an embodiment of the present invention, the amount of the combination of essential oils is about 8% of the weight of the edible film product. In another embodiment, the the combination of essential oils is present in the amount of about 5% by weight of the edible film product. Considering the potency of the combination of essential oils as described in the in vitro studies above, about 1% by weight of the edible film product may also be effective in bactericidal properties. In an embodiment, the amount of the combination of essential oils present is in an amount above 21%. In an embodiment, the amount of the combination of essential oils is present is in amount above 5%. In an embodiment, the amount of the combination of essential oils present in an amount between 6% and 25%.

[0059] The present invention provides edible film formulations for oral mucoadhesion and methods of using and making same. In particular, the edible films of the present inven-

tion include at least three types of film forming agents other than pullulan.

[0060] Applicants have uniquely discovered that the use of a mixture of at least three types of film forming agents, such as maltodextrins, fillers (e.g., microcrystalline cellulose (MCC)) and hydrocolloids (e.g., sodium aliginate), can be effectively utilized to prepare stand alone edible films. The edible films are composed of ingredients that are readily available, can be prepared at lower costs and display similar properties as compared to edible films composed of pullulan. In this regard, the edible films can provide a physiologically acceptable film, which is suitably adapted to adhere to oral surfaces of an oral cavity and rapidly dissolve therein.

[0061] The edible films of the present invention can be utilized to deliver or release oral care agent(s). Such agents include, anti-microbial agents and salivary stimulants to treat, for example, halitosis, dental plaque, gingivitis, xerostomia, dry mouth, like oral conditions or combinations thereof. Further, the oral care edible film can act as a breath freshener effective against malodor.

[0062] The oral cleansing and breath freshening effects of the edible film of the present invention can be achieved by

entrapping the oral care agents within the oral cavity to provide extended efficacy. In this regard, the highly dissolvable edible film can act as a medium through which a pharmaceutically active oral agent can be administered via a mucous membrane of the oral cavity.

[0063] Further, the edible films can include a variety of other suitable ingredients, such as softeners, colorants, flavoring agents, emulsifiers, surfactants, thickening agents, binding agents, sweeteners, fragrances, other like ingredients or combinations thereof.

[0064] In an embodiment, the edible films preferably include a mixture of at least three types of film forming agents, such as maltodextrins, fillers and hydrocolloids. It should be appreciated that the edible film of the present invention can be composed of one or more different compounds associated with each of the at least three types of film forming agents.

[0065] In an embodiment, the maltodextrin component constitutes between about 5% to about 60% by dry weight of the edible film, preferably about 20% to about 40% by dry weight. The maltodextrin component can be processed in any suitable way.

[0066] The hydrocolloid can provide thickness and decrease brit-

tleness of the edible films. The hydrocolloid can include any suitable type, amount and number of hydrocolloids. In an embodiment, the hydrocolloid can constitute between about 10% to about 50% by dry weight of the edible film, preferably about 20% to about 30% by dry weight. The hydrocolloid can be derived from, for example, natural seaweeds, natural seed gum, natural plant exudates, natural fiber extracts, biosynthetic gums, gelatins, biosynthetic process starch or cellulosic materials, alginates, sodium alginate, calcium alginate, carrageenans, guar gum, locust gum, tara gum, gum arabic, ghatti gum, agar gum, xanthan gum, pectin, other like hydrocolloid source material or combinations thereof.

[0067] Any suitable food-grade bulk filler can also be added to the edible film. This can reduce any slimy texture as well as provide structure to the film thereby making it more palatable. In an embodiment, the filler can constitute about 5% to about 30% by dry weight of the film, preferably about 15% to about 25% by dry weight. The filler can include, for example, microcrystalline cellulose, cellulose polymers, such as wood, magnesium and calcium carbonate, ground limestone, silicates, such as magnesium and aluminum silicate, clay, talc, titanium dioxide, mono-

calcium phosphate, di-calcium phosphate, tri-calcium phosphate, other like bulk fillers or combinations thereof.

[0068] It is believed that the unique mixture of at least three film forming agents other than pullulan, for example, a maltodextrin, a hydrocolloid and a bulk filler, can provide a stand alone edible film composition which exhibits many of the same desirable properties exhibited by more expensive pullulan-based edible film. Applicants have desirably discovered that the pullulan-free edible film formulation of the present invention can exhibit, for example, clean mouth feel, clean favor and ease of manufacture similar to currently available pullulan-based films.

[0069] As previously discussed, a variety of other suitable ingredients can be added to the edible film of the present invention. For example, any suitable medicament for oral cleansing, breath freshening or the like can be added to the film formulation. The medicaments can include, for example, a pH control agent, such as urea and buffers, inorganic components for tartar or caries control, such as phosphates and fluorides, a breath freshening agent such as zinc gluconate, an anti-plaque/anti-gingivitis agent, such as cholorhexidene, CPC, and triclosan, a saliva stimulating agent including, for example, food acids such as

citric, lactic, maleic, succinic, ascorbic, adipic, fumaric and tartaric acids, a pharmaceutical agent, a nutraceutical agent, a vitamin, a mineral, other like medicaments or combinations thereof.

[0070] The medicaments can be delivered or released into the oral cavity for effective oral treatment, such as oral cleansing and/or breath freshening. In this regard, the film forming agent of the edible film can act to entrap the medicaments within the oral cavity thereby providing extended efficacy thereof. In doing so, it is believed that the pullulan free edible film compositions of the present invention more uniformly release the medicament into the oral cavity for absorption via open wounds or mucous membrane in a greater manner than could be previously achieved. Moreover, it is also believed that the mixture of film-forming agents of the present invention can entrap the medicament within the oral cavity for an extended period of time to prolong and enhance the effects of the medicament. In addition, by extending the contact time of the medicament within the oral cavity, the medicament is absorbed to a greater extent thereby increasing its bioavailability.

[0071] If reduced levels of film forming agents are utilized, soft-

eners can be used to reduce the brittleness of the resulting films. The softeners, which are also known as plasticizers or plasticizing agents, generally constitute between about up to 20% by dry weight of the film, preferably about 2% to about 10% by dry weight. The softeners can include plasticizers containing, for example, sorbitol and other polyols, glycerin, polyethylene glycol, propylene glycol, hydrogenated starch hydrolysates, corn syrups, other like material or combinations thereof.

[0072] The edible film formulations of the present invention can also include colorants or coloring agents which can be used in any suitable amount to produce the desired color. Coloring agents can include, for example, natural food colors and dyes suitable for food, drug and cosmetic applications. The colorants are typically knows as FD&C dyes and lakes.

[0073] A variety of flavoring agents can also be added to the edible films. Any suitable amount and type of artificial and/or natural flavoring agents can be used in any sensorially acceptable fashion. For example, the flavor can constitute about 0.1% to about 20% by dry weight of the film, preferably about 10% to 15%. The flavoring agent can include, for example, essential oils, synthetic flavors or mixtures

including but not limited to oils delivered from plants and fruits such as citrus oils, fruit essences, peppermint oil, spearmint oil, other mint oils, clove oils, oil of wintergreen, anise and the like, flavor oils with germ killing properties such as menthol, eucalyptol, thymol, like flavoring agents or combinations thereof.

[0074] The flavor can be enhanced and evenly distributed throughout the product by emulsification. Any suitable amount and type of natural and/or synthetic food-grade emulsifier can be used. For example, the emulsifier can include lecithin, food-grade non-ionic emulsifiers, such as fatty acids (C_{10}-C_{18}), mono and diacyl glycerides, ox bile extract, polyglycerol esters, polyethylene sorbitan esters, propolyene glycol, sorbitan monopalmitate, sorbitan monosterate, sorbitan tristerate, enzyme modified lecithin, hyroxylated lecithins, other like emulsifiers or combinations thereof.

[0075] The flavors can be emulsified by any suitable emulsification process, such as mechanical processing, vigorous stirring, intense pressure fluctuations that occur in turbulent flow such as homogenization, sonication, colloid milling and the like.

[0076] The present invention provides methods of producing the

edible film formulations. In general, the edible film formulations are prepared by forming a base solution that includes at least three types of film forming agents, such as maltodextrins, hydrocolloids and fillers and processing the base solution to form an edible film. Typically, the base solution is prepared by adding an initial mixture of dry ingredients to water that is stirred.

[0077] To the base solution, additional ingredients, such as flavor/emulsifier blends, sweeteners, softeners, color, the like or combinations thereof, can be added. In an embodiment, the solution is stirred continuously and heated at a temperature ranging from about 40°C to about 60°C. The solution then can be dried in any suitable manner, thereby, forming the edible film.

[0078] It should be appreciated that any suitable type, number and arrangement of process procedures or steps (i.e. mixing, heating, drying, cooling, addition of ingredients), process parameters (i.e. temperature, pressure, pH, process times) or the like can be utilized.

[0079] By way of example and not limitation, the following examples illustrate various embodiments of the edible film formulations of the present invention.

Table 3. Antimicrobial Thin Film Formulas (% by weight and dry

basis)

Ingredient	Example 11	Example 12	Example 13	Example 14	Example 15
Water	11.00	10.00	10.00	10.00	10.00
Maltodext-rin	26.00	23.23	24.56	25.96	23.00
Sodium Algi-nate	28.79	26.33	21.67	24.32	21.70
Carageenan	8.66	8.51	9.26	7.73	6.54
Microcryst-alline Cellu-lose	8.75	7.02	9.12	9.56	6.58
Hydroxyl-ated Lecithin	2.12	1.86	2.11	3.01	5.50
Glycerin	7.35	6.92	8.33	6.56	6.79
Menthol	2.40	-	-	1.05	-
Sucralose	3.13	3.08	4.42	-	-
High Intensity Sweetener	-	-	-	1.76	1.98
Combo of Es-sential Oils	1.75	12.00	10.48	10.00	17.15
Color	0.05	0.05	0.05	0.05	0.76
Total %	100.00	100.00	100.00	100.00	100.00

Table 4. Antimicrobial Edible Film Formulations (% by weight)

Ingredient	Example 16	Example 17	Example 18	Example 19	Example 20
Maltodextrin	25.05	47.00	31.20	36.80	21.00
Sodium Al-ginate	22.50	-	19.00	-	12.00
Calcium Al-	-	15.15	-	11.45	-

ginate					
Carageenan	-	-	-	-	12.00
Microcrys-talline Cellu-lose	25.75	9.00	18.80	13.00	20.00
Calcium Carbonate	-	2.45	-	-	-
Glycerin	12.25	10.00	8.00	-	9.5
Sorbitol	-	-	-	6.00	1.55
Propylene Glycol	-	-	3.65	5.00	-
Menthol	1.00	0.05	-	1.25	-
Eucalyptol	-	0.05	-	1.00	-
Maleic Acid	-	-	-	-	1.35
Citric Acid	-	-	1.25	-	1.00
Chlorohexi-dene	1.85	-	-	1.00	-
Triclosan	-	1.25	-	1.00	-
Flavor	9.40	11.00	12.00	14.00	10.00
High Inten-sity Sweet-ener	1.25	1.00	1.05	1.45	1.50
Combo of Essential Oils	1.00	3.00	5.00	8.00	10.00
Color	0.05	0.05	0.05	0.05	0.10
Total %	100.00	100.00	100.00	100.00	100.00

Table 5. Antimicrobial Edible Film Formulations (% by weight)

Ingredient	Example 21	Example 22	Example 23	Example 24	Example 25
Maltodextrin	35.00	30.35	28.15	25.00	30.00
Sodium Alginate	22.15	19.10	17.00	28.15	-
Carageenan	-	-	-	-	20.15
Microcrystalline Cellulose	20.00	18.00	17.00	17.00	18.00
Gum Arabic	-	-	11.00	-	-
Glycerin	7.30	15.00	7.30	7.30	7.30
Flavor	11.00	11.00	11.00	11.00	11.00
Lecithin	2.00	2.00	2.00	2.00	2.00
High Intensity Sweetener	1.50	1.50	1.50	1.50	1.50
Combo of Essential Oils	1.00	3.00	5.00	8.00	10.0
Color	0.05	0.05	0.05	0.05	0.05
Total %	100.00	100.00	100.00	100.00	100.00

[0080] In yet another embodiment of the present invention, and effective amount for anti-microbial benefit of the combination of essential oils is present in a confectionery formulation. In an embodiment of the present invention, the amount of the combination of essential oils is present in an amount up to 3% by weight of the confectionery product. In an embodiment of the present invention, the

amount of the combination of essential oils is about 1% of the weight of the confectionery product. In another embodiment, the the combination of essential oils is present in the amount of about 0.01% by weight of the confectionery product. Considering the potency of the combination of essential oils as described in the in vitro studies above, 0.005% by weight of the confectionery product s also effective in bactericidal properties.

[0081] Confectionery products for this invention may be hard candies, chewy candies, coated chewy center candies and tabletted candies. By way of example, the hard candy is primarily comprised of corn syrup and sugar, and derives its name from the fact that it contains only 1.0% and 4% moisture. In appearance, these types of candies are solid, but they are actually supercooled liquids, which are far below their melting points. There are different types of hard candies. Glass types are usually clear or made opaque with dyes; and Grained Types, which are always opaque.

[0082] The continuous making process of the Deposited Glass Types, with a sugar base are as follows. Sugar corn syrup mixture is spread over a cylinder heated by high pressure steam. Rapid head exchange causes the water in the syrup

to evaporate. The cooked syrup is discharged, colors and flavors are added. These can be conveyed directly to hoppers which then discharge directly into molds.

[0083] The candy is conveyed to batch rollers, which shapes and sizes the batch. The candy enters a former, which shapes the individual pieces into discs, balls, barrels, etc. The present invention can be made into any shape, circles, squares, triangles etc, also into animal shapes or any other novelty molding available. The candy is then cooled, wrapped and packaged.

[0084] For Grained Types of candy, water and sugar are the basic components being mixed with other ingredients, and cooked at high temperatures (290°F 310°F), causing the water to turn to steam. The product is transferred to a cooling wheel, where it is collected in about 150 pound batches, placed in a pulling machine to aerate the product, and the flavor is added. The candy is transferred to batch rollers where it is shaped and sized. The candy then enters a former, which shapes the individual pieces. The candy is cooled at a relative humidity of 35% and enters a rotating drum where it is coated with a fine sugar. The candy is then conveyed to the graining room for four hours at 90°F and 60% humidity. The entrapped air and

moisture causes the product to grain.

[0085] The present invention can be of a variety of shapes, flavors and sizes. The present invention may contain sugar or may be sugarless.

[0086] Flavors used in the present invention may be peppermint oils, citrus oils, arvensis, fruit flavors, spearmint oils and the like.

[0087] Colors used in the present invention are colorants are typically known as FD&C dyes and lakes.

[0088] By way of example and not limitation, the following examples illustrate various embodiments of the confectionery formulations of the present invention.

Table 6. Antimicrobial Candy Formulations (% by weight)

Ingredient	Example 26	Example 27	Example 28	Example 29	Example 30
Corn Syrup	44.51	43.25	-	-	48.00
Sugar	53.49	50.00	-	-	47.00
Polyalcohols	-	-	95.20	95.77	-
Flavor	1.00	5.00	3.00	2.00	2.50
Color	0.50	1.00	0.60	0.80	0.50
Combo of Essential Oils	0.50	0.75	1.00	1.23	2.00
High Intensity Sweetener	-	-	0.20	0.20	-

Total %	100.00	100.00	100.00	100.00	100.00	